Trichlorfon Summary Document
Registration Review: Initial Docket
March 2009

Case # 0104

Approved By:

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This Preliminary Work Plan and Fact Sheet summarize the Environmental Protection Agency's current position based on the following documents:

1. Registration Review: Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Trichlorfon, March 3, 2009.
2. Registration Review: Addendum to the Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Trichlorfon, March 12, 2009.
3. Trichlorfon: Human Health Assessment Scoping Document in Support of Registration Review, March 11, 2009.
4. Appendix A: Food/Feed & Non-Food/Non-Feed Uses Considered for Registration Review. July 28, 2008.
5. Screening Level Use Analysis (SLUA) for Trichlorfon. June 6, 2008.
6. Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED). September, 2001. (Available at http://www.epa.gov/pesticides/reregistration/REDs/trichlorfon_tred.pdf)
7. Reregistration Eligibility Decision (RED). Trichlorfon. January 1997. (Available at http://www.epa.gov/pesticides/reregistration/REDs/0104.pdf)

Additional supporting documents for trichlorfon may be found in the docket EPA-HQ-OPP-2009-0097, located on the internet at www.regulations.gov.

I. PRELIMINARY WORK PLAN - Trichlorfon

Introduction:

The Food Quality Protection Act of 1996 mandated a registration review program. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the Environmental Protection Agency (EPA), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program, and will review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration. Where assessments indicate risks above the Agency's level of concern, the Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of trichlorfon.

Trichlorfon was the subject of a 1995 Reregistration Eligibility Decision (RED) and a 2001 Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED). The trichlorfon RED was finalized upon completion of the Organophosphate (OP) Cumulative Risk Assessment in 2006. Trichlorfon is an organophosphate (OP) insecticide registered for nonagricultural, commercial and residential uses, including golf course turf, home lawns, ornamental shrubs and plants, and ornamental fish and bait ponds. Although there are no registered agricultural or other food/feed uses in the U.S., trichlorfon is used in other countries as a pour-on treatment for cattle; this use is classified as a food use in the U.S. and requires a tolerance for imported beef and beef byproducts.

Trichlorfon degrades to dichlorvos (DDVP) in food, water, or the environment. The registration review of trichlorfon also will include an assessment of DDVP resulting from trichlorfon use. DDVP itself is a pesticide active ingredient, and will be assessed in a separate registration review case (case # 0310). The registration review of DDVP also will consider DDVP generated from the use of trichlorfon and naled, both of which degrade to DDVP. Trichlorfon, naled, and DDVP were included in the OP Cumulative Risk Assessment; this assessment did not result in any changes to

Anticipated Risk Assessment and Data Needs

The Agency anticipates updating and revising the ecological risk assessment for trichlorfon (including an endangered species risk assessment) and updating and revising the human health risk assessment. Additional data that the Agency anticipates needing to complete these assessments are specified below.

Ecological Risk:

- A national-level ecological risk assessment was completed in support of the 1995 Trichlorfon RED. This assessment was revised in 2000 to incorporate new data. The Agency has not conducted a risk assessment that supports a complete endangered species determination.

- The primary environmental concerns identified in the 1997 and 2000 environmental fate and ecological risk assessments were acute and chronic risks to birds, mammals, fish, and aquatic invertebrates.

- Mitigation measures specified in the 2001 TRED to reduce occupational handler risks (i.e., limiting broadcast treatments to golf course tees and greens) also are expected to reduce environmental exposure and risk concerns.

- Unlike previous ecological assessments conducted by the Agency for trichlorfon, the ecological risk assessment during registration review will estimate risk from exposure to trichlorfon, and its major degradate DDVP, by evaluating "total trichlorfon residues of concern" (trichlorfon plus DDVP). Submitted data indicate that DDVP is equally or more toxic than trichlorfon to terrestrial and aquatic animals on both an acute and chronic basis.

- The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine whether trichlorfon's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.

- The Agency anticipates needing the following data in order to conduct a complete ecological risk assessment for trichlorfon, including an endangered species assessment:

  Ecological Toxicity Studies:
  - GDLN 850.2100 - Acute Avian Oral Toxicity – passerine (trichlorfon and DDVP)
  - GDLN 850.2200 - Avian Dietary Toxicity Test (trichlorfon)
  - Special Study - Acute Avian Inhalation Study (DDVP)
  - GDLN 850.1075 - Fish Acute Toxicity Test, Estuarine/Marine (trichlorfon)

- GDLN 850.1035 - Mysid Acute Toxicity Test (trichlorfon)
- GDLN 850.1400 - Fish Early Life-Stage Toxicity Test, Estuarine/Marine (trichlorfon)
- GDLN 850.4100, 850.4150 - Terrestrial Plant Toxicity Test, Tier I, Seedling Emergence and Vegetative Vigor (trichlorfon and DDVP)
- GDLN 850.4400 - Aquatic plant toxicity, Tier I (trichlorfon and DDVP)

Environmental Fate Studies:

- GDLN 835.2120 – Hydrolysis (trichlorfon)
- GDLN 835.2410 – Photodegradation in Soil (trichlorfon)
- GDLN 835.4300 - Aerobic Aquatic Metabolism (trichlorfon)
- GDLN 835.1240 - Adsorption/desorption (trichlorfon)
- GDLN 835.4400 - Anaerobic Aquatic Metabolism (trichlorfon)
- GDLN 835.6200 - Aquatic Field Dissipation (trichlorfon)
- GDLN 835.6100 – Environmental Chemistry Methods - soil (trichlorfon)
- GDLN 835.6200 - Environmental Chemistry Methods – water (trichlorfon)

- The Agency seeks additional information, particularly use and usage information, in order to conduct a refined, complete ecological risk assessment, including an endangered species assessment, for trichlorfon. See "Guidance for Commenters" section below.

- Please refer to the documents, *Registration Review: Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Trichlorfon*, March 3, 2009 and *Registration Review: Addendum to the Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Trichlorfon*, March 12, 2009, for a detailed discussion of the Agency's anticipated ecological risk and environmental fate assessment needs.

Human Health Risk:

- The most recent human health risk assessment for trichlorfon was completed in support of the 2001 TRED.

- Based on a new immunotoxicity data requirement for trichlorfon, the Agency expects to reevaluate the toxicity endpoints used for human health risk assessment purposes in the registration review of trichlorfon.

- The dietary exposure (food only) database for trichlorfon is essentially complete. However, a full characterization of the trichlorfon residue profile is needed in order to ensure that the previously conducted dietary exposure assessment included the appropriate residue components and levels. The Agency has requested the registrant to submit supplemental information regarding the previously submitted nature of the residue study, in order to clarify the trichlorfon residue profile.

- The Agency anticipates updating the drinking water exposure assessment for trichlorfon during registration review to directly incorporate drinking water residues into the dietary risk assessment (food and water), as is current Agency policy. This assessment also will consider all sources of DDVP, including direct applications of DDVP as a pesticide active ingredient, as well as uses of trichlorfon and naled, both of which degrade to DDVP.

- Based on the anticipated need to update the drinking water exposure estimate, including the need to consider potential exposures to DDVP, the Agency anticipates conducting new dietary (food and water) and aggregate exposure assessments.

- Tolerances may need to be updated for livestock commodities if supplemental data from the previously required nature of the residue study identifies additional residues of concern.

- The Agency expects that the mitigation specified in the TRED (i.e., limiting broadcast treatment to tees and greens, direct soil application only for ornamentals) reduces the occupational handler and post-application exposure. However, these mitigation measures addressed risks associated with exposure to trichlorfon parent residues only. The Agency intends during registration review to consider potential exposures from DDVP as part of its assessment of occupational risk.

- In the 2006 DDVP RED, the Agency estimated the aggregate risk from all sources of DDVP, including DDVP derived from trichlorfon, in its human health assessment. The Agency's assessment concluded that significant dermal and inhalation exposure to DDVP is not expected from the occupational use of trichlorfon on turf. However, the Agency required trichlorfon registrants to conduct two studies to confirm this conclusion: dermal exposure (875.2400) and inhalation exposure (875.2500). The registrant has submitted waiver requests for these studies, and the Agency is currently reviewing these requests. If it is determined, based on the results of these studies or other new information, that exposure to DDVP resulting from trichlorfon use presents potential risk concerns, the Agency may need to conduct a new occupational risk assessment for trichlorfon.

- Should any of the endpoints or safety factors be revised, or if additional data indicates the potential for significant inhalation or dermal exposure to DDVP, EPA may need to conduct new occupational and residential risk assessments to support the registration review of trichlorfon.

- Should the Agency determine that new information on trichlorfon is available which could potentially impact the OP cumulative risk assessment and result in a risk of concern, the Agency will revisit the cumulative risk assessment.

- The Agency anticipates needing the following data in order to conduct a complete human health effects risk assessment for dietary (food and drinking water), residential, and occupational exposures to trichlorfon under registration review:

- GDLN 870.7800 - Immunotoxicity Study

- Please refer to the *Trichlorfon; Human Health Assessment Scoping Document in Support of Registration Review,* March 11, 2009, available in the docket for a detailed discussion of the anticipated risk assessment and data needs for completing the human health risk assessment.

Timeline:

The Agency has created the following estimated timeline for the completion of the trichlorfon registration review.

Registration Review for Trichlorfon – Projected Registration Review Timeline	
Activities	Estimated Year/Month
Opening the Docket	
Open Docket and Public Comment Period	2009 - March
Close Public Comment	2009 - May
Case Development	
Develop Final Work Plan (FWP)	2009 - August
Issue Data Call-in (DCI)	2010 - April - June
Data Submission	2012 - April – June
Period Preliminary Risk Assessments and Open Public Comment Period	2013 – Oct. – Dec.
Close Public Comment Period	2014 - January –March
Registration Review Decision	
Proposed Registration Review Decision	2014 - April – June
Public Comment Period	2014 - July-September
Final Registration Review Decision & Begin Post-Decision Follow-up	2015
Total (years)	6

Guidance for Commenters:

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments, as well as any additional information or data provided in a timely manner, prior to issuing a final work plan for the trichlorfon case.

- Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

- EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to trichlorfon compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

- Trichlorfon is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://oaspub.epa.gov/tmdl/waters_list.impairments?p_impid=3. The Agency invites submission of any other existing water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process* (see http://www.epa.gov/oppfead1/cb/ppdc/2006/november06/session1-sop.pdf) in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

- There is specific information that will assist the Agency in refining the ecological risk assessment, including any species-specific effects determinations. The Agency is interested in obtaining the following information:

1. Confirmation on the following label information.
    a. sites of application
    b. formulations
    c. application methods and equipment
    d. maximum application rates
    e. frequency of application, application intervals, and maximum number of applications per season and per year
    f. geographic limitations on use
2. Use or potential use distribution (*e.g.*, acreage and geographical distribution of relevant uses).
3. Use history.
4. Median and 90th percentile reported use rates (lbs. a.i./acre) from usage data – national, state and county.
5. Application timing (date of first application and application intervals) by use - national, state, and county.
6. Usage/use information for non-agricultural uses (*e.g.*, golf courses, athletic fields, ornamentals).
7. Directly acquired county-level usage data (not derived from state level data).
    a. maximum reported use rate (lbs. a.i./acre) from usage data – county
    b. median and 90th percentile number of applications – county
    c. total pounds per year – county

d. the year the pesticide was last used in the county/sub-county area
e. the years in which the pesticide was applied in the county/sub-county area

8. Typical application interval (days).
9. State or local use restrictions.
10. Ecological incidents specific to trichlorfon (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency.
11. Monitoring data.

Next Steps:

After the 60-day comment period closes, the Agency will review any comments received in a timely manner and then issue a Final Work Plan for this pesticide.

II. FACT SHEET

Background Information:

- Trichlorfon registration review case number: 0104
- Trichlorfon PC Code: 057901
- Chemical Abstracts Service (CAS) # 52-68-6
- Trichlorfon was first registered in 1955.
- The technical registrant is Bayer CropScience.
- There are nine FIFRA Section 3 active product registrations, one technical product and three Section 24 (c) Special Local Needs registrations.
- There are tolerances for import purposes only, expressed in terms of trichlorfon *per se* [40 CFR §180.198].
- A RED was completed for trichlorfon in 1995.
- The Trichlorfon TRED was completed in 2001. In addition to reassessing tolerances, the Agency also reassessed potential occupational and residential/recreational human health risks as it had received new Outdoor Residential Exposure Task Force (ORETF) data.
- The trichlorfon RED was finalized with the completion of the OP Cumulative Risk Assessment in July 2006. No cumulative risks of concern for trichlorfon were identified in that assessment, and no additional mitigation was specified for trichlorfon.
- Special Review and Reregistration Chemical Review Manager: Kylie Rothwell (rothwell.kylie@epa.gov)
- Registration Division Contact: Akiva Abramovitch (abramovitch.akiva@epa.gov)

Use and Usage Information (For additional details, please refer to the *Screening Level Use Analysis* in the trichlorfon docket.)

- Trichlorfon is an OP insecticide registered for use on golf course turf, home lawns, ornamentals (flowers, trees and shrubs), and ponds (ornamental and bait fish).
- Trichlorfon is used to control a variety of arthropod pests including cockroaches, crickets, silverfish, bedbugs, fleas, cattle grubs, flies, ticks, leafminers, and leaf-hoppers.
- Trichlorfon is available in soluble concentrate/solid, granular, and liquid formulations.
- Trichlorfon can be applied by aerial or ground (hand-held or truck-drawn sprayer) equipment.

Recent Actions:

- The trichlorfon registrant is currently amending product labels to incorporate mitigation measures identified in the TRED.

Ecological Risk Assessment Status

The following are key findings of the most recent ecological risk assessments. Please refer to *Registration Review: Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Trichlorfon*, March 3, 2009 and *Registration Review: Addendum to the Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Trichlorfon,* March 12, 2009, located in the docket, for a detailed discussion of the ecological risk assessment.

- The primary environmental concerns identified in the most recent trichlorfon environmental fate and ecological risk assessments were acute and chronic risks to birds, mammals, fish, and aquatic invertebrates. Trichlorfon is practically non-toxic on an acute contact basis to beneficial terrestrial insects (honey bees).

- The previous ecological risk assessments considered the parent chemical, trichlorfon, only. The major degradate, DDVP, was not considered.

- Mitigation measures specified in the 2001 TRED to address risks to occupational handlers (e.g., limiting broadcast use on golf course turf to tees and greens) are expected to lower environmental exposure and risk concerns.

- EPA initiated a formal consultation with the Services in 1989 regarding trichlorfon impacts on endangered species. The Services issued a biological opinion in 1989, which identified reasonable and prudent alternatives and measures to mitigate potential effects of trichlorfon on endangered species. The opinion classified 79 species as "in jeopardy." The reasonable and prudent measures and alternatives noted in the biological opinion were considered in EPA's County Bulletins. While pesticide users were encouraged to follow the measures in the County Bulletins, they were not enforceable under FIFRA. That biological opinion was based on what are now outdated label instructions and use sites for trichlorfon, and the Agency's assessment was based on methodologies that have since been refined. Therefore, the Agency will be reassessing the uses of trichlorfon during registration review and initiating consultation as appropriate, to determine ultimately what if any enforceable limitations on its use are necessary to ensure protection of federally listed threatened or endangered species and their designated critical habitat.

Human Health Risk Assessment Status

The following are key findings of the human health risk assessments conducted in support of the Trichlorfon TRED. Please refer to *Trichlorfon: Human Health Assessment Scoping Document in Support of Registration Review*, March 11, 2009.

- Trichlorfon risk assessments rely in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, which comprise

the Pesticide Handlers Exposure Database (PHED) and the ORETF studies have been reviewed by the Agency and found on the basis of available evidence to have been neither fundamentally unethical nor significantly deficient relative to standards of ethical research conduct prevailing when they were conducted. There is no barrier in EPA's "Protection of Human Subjects" regulation to reliance on these studies.

Hazard Characterization:

- Trichlorfon, like other OPs, causes cholinesterase inhibition and other neurotoxic effects in all species tested. Neurotoxicity has been observed in acute, subchronic, chronic, and developmental/reproductive toxicity studies.
- In general, based on animal studies, trichlorfon is acutely toxic via the oral route of exposure (Category II), has low inhalation and dermal toxicity (Category III), causes eye irritation (Category II), and is a moderate skin sensitizer. It causes mild skin irritation.
- Cholinesterase inhibition was the toxicity endpoint chosen for the acute and chronic dietary, and short- and intermediate-term dermal and inhalation risk assessments for occupational and residential exposure.

Dietary (Food and Drinking Water):

- There are no domestic food uses for trichlorfon. Trichlorfon is used in other countries as a pour-on treatment for cattle. This use is classified as a food use in the U.S. and, therefore, requires an import tolerance for beef and beef byproducts.
- The most recent dietary assessment, conducted in support of the 2001 Trichlorfon TRED, did not evaluate potential exposure to DDVP in food or drinking water. In this assessment, the Agency concluded that dietary risks from food only for both acute and chronic exposure are not of concern.
- When food and drinking water are aggregated, potential risks of concern were identified for children 1-6 years. The Agency believed these modeled estimates for exposure to trichlorfon residues in surface water sources of drinking water overestimated the dietary risk for several reasons, including the lack of an appropriate exposure model to assess surface water concentrations resulting from pesticide applications to turf. Additionally, the most recent assessment did not directly incorporate drinking water residues into the dietary risk assessment, as is current policy.

Residential and Recreational:

- There is short-term exposure to residential handlers via dermal and inhalation routes from the handling, mixing, loading and application of trichlorfon to residential lawns.
- Short- and intermediate-term post-application exposure to trichlorfon also can occur to adults and children playing on treated lawns.
- The most recent assessment indicated that residential handler and post-application risks are below the Agency's level of concern.

Aggregate:

- In the most recent aggregate risk assessment, the Agency's level of concern was exceeded for the population subgroup, children 1-6, when the source drinking water is from surface water sources; levels of concern were not exceeded when considering ground water sources.
- Based on the conservative trichlorfon assessment and the limited use patterns, the Agency did not believe that aggregate risks were of concern.

Occupational:

Handler:

- The potential occupational handler exposure routes for trichlorfon are dermal and inhalation. Assessments for short-term (1-30 days) and intermediate-term (1-6 months) exposure durations are relevant for current trichlofon registrations; chronic exposures are not anticipated based on current use patterns.
- The most recent occupational exposure assessment indicated risks above the Agency's level of concern for several exposure scenarios (golf course turf and ornamental fish/bait ponds). The Agency specified label amendments (e.g., prohibiting broadcast use on golf course fairways; requiring applicators to use truck-drawn spraying rigs for ponds greater than one acre) that were expected to mitigate risks.

Post-application:

- In the most recent post-application exposure assessment, risk to workers in ornamental nurseries exceeded the Agency's level of concern. The 2001 TRED specified mitigation prohibiting foliar application to ornamentals and only allowing application to soil at the base of the plant. Direct soil application to ornamentals was expected to effectively mitigate risk concerns.

Cumulative Risk Assessment:

- The Agency has determined that trichlorfon shares a common mode of action with other OPs and was part of the OP cumulative risk assessment which was completed in 2006. No cumulative risks of concern for trichlorfon were identified in that assessment, and no additional mitigation was specified for trichlorfon.

Incidents

- On October 20, 2008, a preliminary review of the Ecological Incident Information System database indicated four reported trichlorfon incidents occurring between 1973 and 2003. Three of the trichlorfon incidents involved aquatic animals and one involved a terrestrial animal; all were associated with mortality of the affected animals. The certainty categories for the four incidents ranged from possible to probable, and two of the incidents involved registered uses while the remaining two involved misuses. Three of the incidents involved additional chemicals besides trichlorfon. Trichlorfon residues were reported in only one of the incident reports.

- In October 2008, an updated review of trichlorfon incident reports was prepared by consulting the OPP Incident Data System (IDS) for reports of poisoning incidents occurring in the United States from 2000 to the present. The evaluation of incident data for trichlorfon has identified 25 incidents; symptoms appear generic and not confirmed to be related to exposure. There is no clear evidence of a trend or exposure pattern. Therefore, at this time, there are no remarkable case reports which suggest a plausible association between a moderate or severe health outcome and exposure to trichlorfon, nor can we discern any suggestion of a trend or pattern regarding the health effects due to the alleged exposure to trichlorfon. The current review of the incident data does not warrant further investigation at this time.

Tolerances and International Harmonization

- There are no MRLs for trichlorfon in Canada, Mexico or through Codex; thus, there are no international harmonization issues to resolve. There are import tolerances in the U.S. for beef and beef byproducts.

Data Call-In (DCI) Status

- As a result of the DDVP RED, three studies (875.2400 - dermal exposure, 875.2500 - inhalation exposure, and 835.6100 terrestrial field dissipation) were required for trichlorfon product registrations (GDCI-057901-27123) to confirm the Agency's conclusions that significant drinking water or dermal/inhalation exposure to DDVP are not expected from the use of trichlorfon on turf. The registrant has submitted waiver requests for these studies, and the Agency is in the process of reviewing these requests.

- A UV/Visible Absorption study (830.7050), submitted in response to the TRED DCI (GDCI-057901-17880), is currently under review.

- The Nature of the Residue in Cattle (860.1300), required in GDCI-057901-17604, is not completely satisfied. The trichlorfon registrant needs to provide additional information regarding the submitted study in order to fulfill this guideline. This information was required in a March 2009 letter to the registrant, with a due date of June 15, 2009.

- The Prenatal Developmental Toxicity, Rat, (870.3700) required in GDCI-057901-16166, is still outstanding. The submitted prenatal developmental toxicity study in rats is unacceptable because a No Observed Adverse Effect Level was not established. This study is needed to conduct a complete and comprehensive analysis of potential critical pre- and post-natal toxicological effects. A new study was required in a March 2009 letter to the registrant, with a due date of March 15, 2011.

- The Developmental Neurotoxicity (DNT) Study (870.6300) required in GDCI 057901-17839 has been reviewed and found to be acceptable. However, a determination of whether the guideline has been fully satisfied is pending the results of the Agency's comprehensive review of all available positive control data.

Labels:

The following table lists active Section 3 and 24 (c) SLN labels for trichlorfon.

Registration No.	Company	Formulation
432-1282	Bayer Environmental Science	Dipterex Technical Insecticide
432-1298	Bayer Environmental Science	Dylox 80 Concentrate
432-1308	Bayer Environmental Science	Dylox 6.2 Granular Insecticide
432-1326	Bayer Environmental Science	Dylox 80 SP Turf and Nursery Insecticide
432-1289	Bayer Environmental Science	Dylox 80 Turf and Ornamental Insecticide
432-1464	Bayer Environmental Science	Dylox 420 SL Turf and Ornamental Insecticide
432-1394	Bayer Environmental Science	Dylox Grub Control Insecticide
9198-110	The Andersons Lawn Fertilizer Division, Inc.	The Andersons Tee Time Insecticide with 6.2% Dylox
72155-83	Bayer Advanced	Dylox 9.3% Insect Granules
72155-33	Bayer Advanced	Dylox Insect Granules
FL03001200 24 (c) (432-1289)	Bayer Environmental Science	Dylox 80 Turf and Ornamental Insecticide
AR98000300 24 (c) (432-1289)	Bayer Environmental Science	Dylox 80 Turf and Ornamental Insecticide
MO99000500 24 (c) (432-1289)	Bayer Environmental Science	Dylox 80 Turf and Ornamental Insecticide

- Active Section 3 labels for trichlorfon can be obtained from the Pesticide Product Label System (PPLS) website: http://oaspub.epa.gov/pestlabl/ppls.home.

III. GLOSSARY of TERMS and ABBREVIATIONS

ai Active Ingredient
DCI Data Call-In
DNT Developmental Neurotoxicity
DWLOC Drinking Water Level of Comparison
EEC Estimated Environmental Concentration
EPA Environmental Protection Agency
FDA Food and Drug Administration
FIFRA Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA Federal Food, Drug, and Cosmetic Act
FQPA Food Quality Protection Act .
LOC Level of Concern
LOAEL Lowest Observed Adverse Effect Level
µg/g Micrograms Per Gram
µg/L Micrograms Per Liter
mg/kg/day Milligram Per Kilogram Per Day
mg/L Milligrams Per Liter
MOE Margin of Exposure
MRID Master Record Identification (number). EPA's system of recording/tracking submitted studies.
MUP Manufacturing-Use Product
NA Not Applicable
NAWQA USGS National Ambient Water Quality Assessment
NPDES National Pollutant Discharge Elimination System
NR Not Required
NOAEL No Observed Adverse Effect Level
OPP EPA Office of Pesticide Programs
OPPTS EPA Office of Prevention, Pesticides and Toxic Substances
PAD Population Adjusted Dose
PCA Percent Crop Area
PDP USDA Pesticide Data Program
PHED Pesticide Handler's Exposure Data
PHI Preharvest Interval
ppb Parts Per Billion
PPE Personal Protective Equipment
ppm Parts Per Million
PRZM/ Tier II Surface Water Computer Model
EXAMS
Q1* The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC Raw Agriculture Commodity
RED Reregistration Eligibility Decision
REI Restricted Entry Interval
RQ Risk Quotient
SCI-GROW Tier I Ground Water Computer Model
SAP Science Advisory Panel
SF Safety Factor
SLN Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI Technical Grade Active Ingredient
USDA United States Department of Agriculture
UF Uncertainty Factor
WPS Worker Protection Standard